# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY and CELLULAR RESEARCH, INC.

C.A. No. 18-1800-RGA

Plaintiffs,

v.

10X GENOMICS, INC.

Defendant.

# DEFENDANT 10X GENOMICS'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

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### I. NATURE AND STAGE OF THE PROCEEDINGS

On November 15, 2018, Plaintiffs Becton, Dickinson and Company and Cellular Research, Inc. (collectively, "BD") filed a patent infringement complaint against Defendant 10X Genomics, Inc. ("10X"). D.I. 1 ("Original Complaint"). On January 18, 2019, 10X filed a motion to dismiss based on § 101 ineligibility and other issues. D.I. 8. On February 8, 2019, BD filed its First Amended Complaint. D.I. 15 ("Complaint"). That Amended Complaint asserts that 10X is infringing 11 patents, grouped by BD in its Complaint into two families: the 7 "Fodor patents" (U.S. Patent Nos. 8,835,358 ("the 358 patent"); 9,315,857; 9,816,137; 9,290,809; 9,290,808; 9,708,659; and 9,845,502, included as Exhibits 1-7 to the Complaint, D.I. 15-1) and the 4 "Fan patents" (U.S. Patent Nos. 9,567,645; 9,567,646; 9,598,736; and 9,637,799). D.I. 15, ¶ 2, 92-358. 10X has filed a motion under Rule 12(b)(6) to dismiss portions of the Complaint for failure to state a claim upon which relief can be granted and respectfully submits this opening brief in support.

### II. INTRODUCTION AND SUMMARY OF THE ARGUMENT

- 1. Of the 11 patents asserted by BD in this case, the 7 patents in the "Fodor" family are directed to the abstract (and patent-ineligible) idea of using different labels to identify different objects. They each claim, in various forms, the abstract idea of labeling different nucleic acid molecules (like DNA) with different labels. Because this amounts to nothing more than an attempt to limit the application of the abstract idea to a particular technological environment (DNA and nucleic acids), the Fodor patents are directed to an ineligible abstract idea under *Mayo* step 1. The Fodor patents also admit in their specification that the other claimed elements (well-known laboratory techniques like "attaching" labels to DNA and "amplifying", "detecting", and "sequencing" DNA) were routine and conventional. The claims thus fail to add "significantly more" to the abstract idea and so are invalid under 35 U.S.C. § 101.
  - 2. In an effort to salvage the patent ineligible claims of the Fodor patents following

10X's first motion to dismiss, BD amended its original complaint to add conclusory, boilerplate allegations that the Fodor claims are not directed to an abstract idea and that their elements were not routine, conventional, or well-known. However, as this and other courts have held, such conclusory assertions of the legal conclusion are insufficient to establish patent eligibility even at the motion to dismiss stage—particularly where, as here, BD's assertions are also contradicted by the specifications' own admissions regarding what was already well-known in the art. *IPA Techs*. *v. Amazon*, No. 16-1266-RGA, 2019 WL 259100, at \*5, 7, 10-12 (D. Del. Jan. 18, 2019).

3. Independent of 10X's § 101 arguments, because the Amended Complaint contains no pleadings supporting infringement of the Fodor 809 patent by 10X's 5' Single Cell products (count 4) and no pleadings supporting infringement of any of the 4 Fan patents by 10X's Spatial Transcriptomics products (counts 8-12), those counts should be dismissed as to those 10X products.

### III. STATEMENT OF FACTS

BD alleges in the body of counts 1-7 of the Complaint that 10X infringes "at least" one claim from each of the 7 Fodor patents: 358 patent claim 6, and claim 1 from each of the 502, 857, 137, 659, 808, and 809 patents. D.I. 15, ¶¶ 101-11, 126-39, 154-70, 185-87, 204-16, 231-40, 255-68. Through high-level claim chart exhibits, BD also asserts that 10X products satisfy additional dependent claims. *Id.*, ¶¶ 112, 140, 171, 188, 217, 241, 269. BD's Original Complaint stated that claim 6 of the 358 patent and claim 1 of each of the other Fodor patents "is representative" of the claims in each of the Fodor patents. D.I. 1, ¶¶ 88, 107, 129, 154, 167, 187, 205.

The 358 patent was filed December 15, 2010 and on its face identifies a provisional application dated December 15, 2009. D.I. 15 Ex. 1 ("358 patent") at 1. The 6 other Fodor patents each state that they are continuations or continuations-in-part dating back to that same application and also identify the same provisional application. D.I. 15 Exs. 2-7 at 1. The Fodor patents' specifications do not assert that attaching, amplifying, detecting, sequencing, or the other claimed

elements were novel or not conventional in December of 2009—to the contrary, the specifications admit that these claim elements were known in the art (as discussed below).

## IV. LEGAL STANDARD: INVALIDITY UNDER 35 U.S.C. § 101.

The *Alice* decision reaffirmed the two-step framework in *Mayo Collaborative Services v*. *Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), used to "distinguish[] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). In assessing patent ineligibility, the Court must determine (1) if the claim is directed to ineligible subject matter such as an abstract idea, and if so, (2) whether there are sufficient inventive elements that the invention is "significantly more" than an ineligible concept. *Id*.

The Supreme Court made clear that "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Alice*, 134 S. Ct. at 2355, 2358. Further, the Federal Circuit confirmed that where claims are directed to ineligible subject matter (even if the ineligible subject matter is innovative or groundbreaking), merely "appending routine, conventional steps to a [the ineligible subject matter], specified at a high level of generality, is not enough to supply an inventive concept." *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377-78 (Fed. Cir. 2015).

Patentability under 35 U.S.C. § 101 is a threshold legal issue. *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Accordingly, the § 101 inquiry is properly raised at the pleadings stage if it is apparent from the face of the patent that the asserted claims are not directed to eligible subject matter. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) ("Patent eligibility has in many cases been resolved on motions to dismiss"); *Cleveland Clinic Found v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017). In those situations, claim construction is not required to conduct a § 101 analysis. *Genetic Techs. Ltd v. Merial LLC.*, 818 F.3d 1369, 1374

(Fed. Cir. 2016). A court need not individually address each claim of the patents if the court identifies a representative claim and "all the claims are substantially similar and linked to the same abstract idea." *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1359 (Fed. Cir. 2014). This Court has repeatedly granted motions to dismiss based on § 101. *See, e.g., Tangelo IP v. Tupperware Brands Corp.*, No. 18-cv-692-RGA, 2018 WL 6168083 (D. Del. Nov. 26, 2018); *Finnavations LLC v. Payoneer, Inc.*, No. 18-444-RGA, 2018 WL 6168618 (D. Del. Nov. 26, 2018); *Broadsoft, Inc. v. Callwave Commc'ns, LLC*, 282 F. Supp. 3d 771 (D. Del. 2017); *Callwave Commc'ns LLC v. AT&T Mobility LLC*, 207 F. Supp. 3d 405 (D. Del. 2016).

"[A]t the motion to dismiss stage, factual allegations in the complaint which contradict the specification or the claims need not be credited as true under the Rule 12(b)(6) analysis." *IPA Techs.*, 2019 WL 259100, at \*5, 7, 10-12. "In a situation where the specification admits the additional claim elements are well-understood, routine, and conventional, it will be difficult, if not impossible, for a patentee to show a genuine dispute." *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1371 (Fed. Cir. 2018) (denial of rehearing en banc). The court is "not required to credit bald assertions or legal conclusions improperly alleged in the complaint." *In re Rockefeller Ctr. Props., Inc. Secs. Litig*, 311 F.3d 198, 216 (3d Cir. 2002).

### V. ARGUMENT

- A. The Fodor Patents Are Invalid Under § 101.
  - 1. The Claims Of The Fodor Patents Are Directed To The Abstract Idea Of Labeling Different Objects With Different Labels.

The claims of the Fodor patents are directed to the abstract idea of labeling different objects with different labels. This concept is as old as the scientific method and is familiar to every student in any introductory science class—when performing an experiment, one needs a control and an experiment and will label them accordingly (whether that means written labels of "control" and "experiment" or "test 1" and "test 2" or "sample A" and "sample B" or some other form of labeling

such as placing one in a green cup and one in a blue cup). Even outside of the context of scientific experiments, using different labels to differentiate and distinguish between different instances of similar objects is commonplace. For example, different instances of the same model of a television set are given different serial numbers for warrantee or recall purposes; people attending a convention are given different name tags; and different books in a library are given different classification numbers (under the Dewey Decimal System) and are assigned different International Standard Book Numbers (ISBNs) (by the Library of Congress). The Fodor patents did not invent this idea—they simply take this abstract idea and attempt to limit the use of the idea to the particular technological environment of DNA (and other nucleic acids) by adding "attaching", "amplifying", and "detecting" steps and other similarly generic techniques that were well-known and conventional before 2009 (the earliest provisional application). The claim language and intrinsic record confirm this. BD's conclusory attorney argument to the contrary in its Complaint is legally insufficient to defeat 10X's Motion and is also contrary to the specification itself.

Claim 6 of the 358 patent is nakedly directed at the abstract idea of labeling different objects (two or more "nucleic acid molecules", e.g., portions of DNA) with different labels ("a plurality of nucleic acid label-tags with different sequences"). 358 patent at claim 6. Specifically, it claims a method that comprises a step (a) of combining "at least two distinct target nucleic acid molecules" (the different objects) "with a pool of nucleic acid label-tags" where "a plurality of [the] nucleic acid label tags" have "different sequences" (the different labels). *Id.* It then requires an "attaching" step (b) of "attaching at least two nucleic acid label-tags from the pool . . . to the at least two distinct target nucleic acid molecules"; an "amplifying" step (c) described generically without any specifics regarding what amplification technique is to be used; and then a "detecting" step (d) also described generically without any specific or concrete requirements:

358 patent Claim 6	Summary
6. A method comprising:	Preamble
(a) combining a mixture comprising at least two distinct target nucleic acid molecules with a pool of nucleic acid label-tags, wherein the pool of nucleic acid label-tags comprises a plurality of nucleic acid label-tags with different sequences;	Different molecules ("two distinct target nucleic acid molecules") and Different labels ("a pool of nucleic acid label-tags")
(b) attaching at least two nucleic acid label-tags from the pool of nucleic acid label-tags to the at least two distinct target nucleic acid molecules to obtain at least two label-tag-target nucleic acid molecules, wherein the distinct target nucleic acid molecules have different sequences from one another;	Generic, conventional attaching techniques
(c) amplifying at least a portion of the label-tag-target nucleic acid molecules, wherein an amplified portion of the label-tag-target nucleic acid molecules comprises at least a portion of said target nucleic acid molecule; and	Generic, conventional amplifying techniques
(d) detecting an amplified product of step (c).	Generic, conventional detecting techniques

*Id.* Though the claim includes "nucleic acid molecules" and "nucleic acid label-tags", these elements merely attempt to limit application of the abstract idea to the technological environment of DNA biochemistry, which does not convert it to eligible matter. *Alice*, 134 S. Ct. at 2355, 2358.

For purposes of the *Mayo* analysis, claim 6 of the 358 patent (claiming labeling different molecules with different labels together with conventional attaching, amplifying, and detecting techniques) is representative of each of the other claims of the Fodor patents asserted in counts 1-7 of BD's Complaint.<sup>1</sup> As discussed below, the other Fodor claims are all substantially similar to claim 6 and are directed to the same abstract labeling idea. Indeed, in its Original Complaint, BD

<sup>&</sup>lt;sup>1</sup> BD's First Amended Complaint asserts additional claims from the Fodor patents, relying on high-level claim chart exhibits. D.I. 15, ¶¶ 112, 140, 172, 189, 218, 242, 270. BD also adds the conclusory assertions that claim 6 of the 358 Patent "is not substantially similar to nor linked to any abstract idea, much less the same abstract idea as" "the other asserted claims." (*id.*, ¶¶ 100, 125, 153, 184, 203, 230, 254) and that the asserted dependent claims "are not directed to an abstract idea and recite inventive concepts for additional reasons" (*id.*, ¶¶ 99, 124, 152, 183, 202, 229, 253). What these conclusory assertions fail to do (and what BD must do to overcome 10X's showing of representativeness) is identify specific claims and claim limitations that are different from claim 6 and explain why those limitations alter the § 101 analysis. *See Content Extraction*, 776 F.3d at 1348 (affirming use of representative claims where Plaintiff did not "identify any other claims as purportedly containing an inventive concept" and failed to differentiate any of the other claims); *IPA Techs.*, 2019 WL 259100, at \*5. Because BD's conclusory assertions fail to "present any meaningful argument for the distinctive significance of any claim limitations not found in the representative claim", the Court can treat 358 Patent claim 6 as representative for this Motion. *Berkheimer*, 881 F.3d at 1365.

admitted that "Claim 6 of the '358 patent ... is representative" (at least of the other claims of the 358 Patent) and made the same statement about claim 1 of each of the other Fodor patents. D.I. 1, ¶¶ 88, 107, 129, 154, 167, 187, 205. Treating 358 claim 6 as representative for the § 101 analysis is thus consistent with BD's own Original Complaint. As addressed in the analysis of step 2 below, the other claims of the Fodor patents add (at most) only conventional, routine elements to the same abstract idea reflected in claim 6 of the 358 patent, further confirming that claim 6 is representative.

Like 358 patent claim 6, claims 1 of the 857, 137, 808, and 502 patents are method claims directed to the same abstract idea of labeling different objects with different labels. See 857 patent claim 1 ("attaching a plurality of diverse label-tags to a nucleic acid target . . ." and then "amplifying" and "detecting" the "labeled targets" to "determin[e] the number of copies of the nucleic acid target"); 2 137 patent claim 1 ("attaching a plurality of primers to the plurality of nucleic acids . . . wherein each primer . . . comprises a different variable label region") and claim 10 (adding "amplifying" and "detecting" steps); 808 patent claim 1 ("combining . . . a plurality of target molecules . . . with a plurality of diverse label-tag [sic]", "amplifying", and "sequencing at least a portion of the amplified product"), and 502 patent at claim 1 ("combining each of a target molecule . . . with a label-tag", "hybridizing the label-tag . . . to the target molecule", "amplifying", and "sequencing at least a portion of the plurality of amplified products").

Although claims 1 of the 809 and 659 patents are "composition" and "system" claims (respectively), they are also directed to this same abstract idea. See 809 patent at claim 1 ("a composition comprising a plurality of oligonucleotide labels . . .") and claim 2 ("claim 1, further comprising a set of n target molecules hybridized to said plurality of oligonucleotide labels."); 659 patent at claim 1 ("a system for counting n . . . comprising:" "a) a diverse set of labels . . .", "b) a plurality of reaction vessels for attaching a label . . . to each occurrence of the nucleic acid target

<sup>&</sup>lt;sup>2</sup> Emphasis is supplied, and internal citations are omitted throughout unless otherwise noted.

molecules . . . ", and "c) processing software for counting n from a number of labeled nucleic acid target molecules detected."). Like claim 6 of the 358 patent (and the method claims of the other Fodor patents), these claims amount to nothing more than the abstract idea of using different labels to label different objects combined with generic, well-known, routine laboratory techniques. The claims do not include any limitations directed at improving the well-known techniques of attaching, amplifying, detecting, or sequencing DNA apart from adding the abstract idea.

The specification of the Fodor patents<sup>3</sup> confirms that this abstract idea—using different labels for different molecules—is the (purportedly) inventive aspect of the claims. The patents are titled "Digital Counting Of Individual Molecules By Stochastic Attachment Of Diverse Labels"—i.e., counting of molecules by attaching different labels to them. D.I. 15-1 (Exs. 1-7). The Abstract focuses on this same abstract labeling idea:

Compositions, methods and kits are disclosed for high-sensitivity single molecule digital counting by the stochastic *labeling of a collection of identical molecules by attachment of a diverse set of labels.* . . . This stochastic transformation relaxes the problem of counting molecules from one of locating and identifying identical molecules to a series of binary digital questions *detecting whether preprogrammed labels are present*.

358 patent at Abstract.<sup>4</sup> As does the "Field of the Invention" section: "Methods, compositions and products for counting individual molecules by stochastic *attachment of diverse labels from a set of labels*, followed by amplification and detection are disclosed." *Id.* at 1:11-17.

The "Background of the Invention" section acknowledges the existence of many known, conventional techniques already "developed to measure the relative abundance of different molecules" (*id.* at 2:45-47) such as: "microarrays and sequencing" (*id.* at 2:47); "PCR" and "digital PCR" (*id.* at 2:53-3:25); and various "hybridization-based techniques" (*id.* at 1:32-2:34). The

<sup>&</sup>lt;sup>3</sup> Because each of the other asserted Fodor patents is a continuation or continuation-in-part of the 358 patent application, citations throughout are to the 358 patent's specification. Unless otherwise noted, the same or similar disclosures are present in each of the other asserted Fodor patents (although the 857 patent frequently replaces the word "label(s)" with "label-tag(s)").

<sup>&</sup>lt;sup>4</sup> The Abstract of the 857 patent contains slightly different language but is substantively the same.

background section identifies two purported shortcomings of the prior art: that "few techniques are available to determine the absolute number of molecules in a sample" and that "[m]ethods for estimating the abundance or relative abundance of genetic material having increased accuracy of counting would be beneficial." *Id.* at 2:47-49 and 1:29-31.

However, the "Summary of the Invention" confirms that any purported benefits from the inventions come only from the abstract idea of labeling different molecules with different labels:

High-sensitivity single molecule digital counting by the stochastic labeling of a collection of identical molecules is disclosed. . . .

Methods are disclosed herein for digital counting of individual molecules of one or more targets. In preferred embodiments the targets are nucleic acids, but may be a variety of biological or non-biological elements. *Targets are labeled so that individual occurrences of the same target are marked by attachment of a different label* to difference [sic] occurrences. . . . Preferably the labels are different sequences that tag or mark each target occurrence uniquely.

*Id.* at 3:26-31, 3:55-64.<sup>5</sup> Indeed, the Summary of the Invention is devoid of any discussion at all of the other various (known, conventional) laboratory techniques that appear in the claims (let alone any specifics about *how* to attach, hybridize, amplify, detect, or sequence nucleic acid molecules, or even how to form or deliver the labels). *See id.* at 3:26-4:26.

The Detailed Description of the Invention similarly confirms that the purported invention amounts to nothing more than the abstract idea of labeling different molecules with different labels, combined with known, conventional techniques like amplification, detection, and microarrays:

Methods for performing single molecule digital counting by the stochastic labeling of a collection of identical molecules are disclosed. As illustrated in FIGS. 1, 2A and 2B, each copy of a molecule (from a collection of identical target molecules 103) randomly captures a label by choosing from a large, non-depleting reservoir of diverse labels 101. . . Once the molecules are labeled each has been given a unique identity and can now be separately detected.

Id. at 17:66-18:9; id. at Fig. 2A<sup>6</sup> (depicting the pool of different labels (l<sub>1...960</sub>) for attaching to 4

<sup>&</sup>lt;sup>5</sup> The 857 patent again contains substantively the same disclosure. See 857 patent at 4:21-33.

<sup>&</sup>lt;sup>6</sup> In the 857 patent, this same figure is Figure 1 instead of Figure 2A.

copies of the target molecule (t<sub>1</sub>-t<sub>4</sub>) which are then amplified and detected using known, conventional techniques); *see also*, *id.* at Figs. 1-2B and 18:32-19:12 (describing Figs. 1-2B).

The prosecution history, part of the intrinsic record, confirms that this abstract idea was the purportedly novel aspect necessary for the claims to issue. In response to an obviousness rejection, the applicant had an interview with the examiner and convinced the examiner that the prior art reference "does not teach attaching label-tags to two distinct target nucleic acid molecules as claimed in [claim 6]." **Ex. A** (March 4, 2014 Applicant Response) at 11;7 see also **Ex. B** (Oct. 3, 2013 non-final rejection); **Ex. C** (interview summary); and **Ex. D** (Notice of Allowance). The other elements alone (attaching, amplifying, and detecting) were not sufficient to lead to allowance.

As this Court has found, claims that "describe concepts 'long-practiced in our society' have been found directed to an abstract idea under *Alice* step one." *Tangelo IP, LLC v. Tupperware Brands Corp.*, No. 18-692-RGA, 2018 WL 6168083, at \*6 (D. Del. Nov. 26, 2018) (citing *Intellectual Ventures I LLC v. Capital One Bank*, 792 F.3d 1363, 1369-70 (Fed. Cir. 2015); *Content Extraction*, 776 F.3d at 1347); *LendingTree, LLC v. Zillow, Inc.*, 656 F. App'x 991, 996-97 (Fed. Cir. 2016); *In-Depth Test, LLC v. Maxim Integrated Products, Inc. et al.*, No. 14-887-CFC 2018 WL 6617142, at \*5 (D. Del. Dec. 18, 2018); *Guada Techs. LLC v. Vice Media, LLC*, No. 17-1503-RGA, 2018 WL 4441460, at \*7-8 (D. Del. Sept. 17, 2018); *see also, e.g., Intellectual Ventures I LLC v. AT&T Mobility II LLC*, 235 F. Supp. 3d 577, 594 (D. Del. Dec. 30, 2016); *Idexx Labs., Inc. v. Charles River Labs.*, No. 15-668-RGA, 2016 WL 3647971, at \*4 (D. Del. Jul. 1, 2016); and *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (finding receiving, generating, analyzing, and/or reporting information abstract because they could be performed by a human). Courts have also specifically found labeling or organizing information to be abstract. *E.g., Gonzalez v. Infostream Grp., Inc.*, No. 2:14-cv-906-JRG, 2016 WL 1643313, at \*4 (E.D. Tex.

<sup>&</sup>lt;sup>7</sup> What issued as claim 6 of the 358 patent was claim 39 at the time of the applicant response.

Apr. 25, 2016) ("gathering and labeling information to facilitate efficient retrieval"); *eDekka LLC v. 3balls.com, Inc.*, No. 2:15-CV-541 JRG, 2015 WL 5579840, at \*3 (E.D. Tex. Sep. 21, 2015) ("storing and labeling information"); *Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1327 (Fed. Cir. 2017) ("creating an index and using that index to search for and retrieve data"); *CyberFone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 F. App'x 988, 992 (Fed. Cir. 2014) ("collecting information in classified form, then separating and transmitting that information according to its classification"); *Cogent Med., Inc. v. Elsevier Inc.*, 70 F. Supp. 3d 1058, 1063 (N.D. Cal. 2014) ("maintaining and searching a library of information").

In *Tangelo*, this Court granted a motion to dismiss based on § 101 ineligibility, finding that the claims were directed to a long practiced abstract idea applied in a particular technological environment (there, a generic computer) without any added inventive concept:

Rather, I believe the '005 patent claims are directed to *the abstract idea of using an identifier* to allow a reader of a printed publication to access related information not in the printed publication—the same concept long practiced by systems of sales representatives and printed product catalogs. . . .

The '005 patent claims do not have an inventive concept that renders them patent eligible. Claim 1 merely applies the abstract idea of using a catalog identifier to obtain additional product information in a generic computer environment.

Tangelo, 2018 WL 6168083, at \*4.

The claims of the Fodor patents similarly fail under step 1 because they are directed to the long-practiced idea of labeling different objects with different labels applied in the particular technological environment of DNA (and other nucleic acid molecules). Merely applying this "old solution" of different labels in the particular technological environment of DNA is insufficient to produce patent-eligible claims. *Alice*, 134 S. Ct. at 2358 ("the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment"); *Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1330 (Fed. Cir. 2017) ("An abstract idea does not become nonabstract by limiting the invention to a

particular field of use or technological environment, such as the Internet."); *Finnavations*, 2018 WL 6168618, at \*4-5 ("the claims here merely apply an 'old solution' (bookkeeping) in a computer environment without specifying any non-conventional way to accomplish or practice the idea.").

As in *Tangelo*, *Finnavations*, *Intellectual Ventures*, *Content Extraction*, and many similar cases, in this case humans have long performed the abstract idea of using different labels to label or identify different instances of an object, including using serial numbers to distinguish between television sets, Dewey Decimal card catalogue numbers to distinguish between books in the library, labels on test tubes to distinguish between samples in an experiment, or even name tags to distinguish between attendees at a convention or meeting. Attempting to limit the application of that abstract idea to DNA (and other nucleic acid molecules) does not save the claims under step 1 any more than would limiting the application of the idea to the Internet or to a generic computer.

# 2. The Claims Of The Fodor Patents Add Only Routine, Conventional DNA Laboratory Techniques To The Abstract Idea.

Because the asserted claims of the Fodor patents are directed to an abstract idea under step 1, they can satisfy § 101 only if they can survive *Mayo* step 2 by reciting sufficient additional inventive elements such that the invention is "significantly more" than the ineligible abstract idea. *Alice*, 134 S. Ct. at 2357. They cannot, because they do not recite *any* additional inventive elements. Instead, the claims recite only the abstract labeling idea together with generic, routine, well-known laboratory techniques for working with DNA and other nucleic acid molecules (like attaching, hybridizing, amplifying, detecting, and sequencing). The specification repeatedly admits that these techniques were known and conventional before the Fodor patents.

In contrast to the many discussions in the specification of the importance of labeling different molecules with different labels (the abstract idea addressed above), the specification describes the other elements of the asserted claims of the Fodor patents as routine and conventional. Indeed, in addition to the many known techniques for counting molecules described

in the Background to the Invention (358 patent at 1:18-3:25), even the "Detailed Description of the Invention" begins by explaining that "[t]he invention has many preferred embodiments *and* relies on many patents, applications and other references for details known to those of the art" (id. at 5:63-65) and then spends six columns describing numerous known, routine lab techniques and citing a host of prior art patents, articles, and lab manuals (id. at 5:65-11:22, 12:40-13:8).

Representative claim 6 of the 358 patent adds "attaching", "amplifying", and "detecting" steps to the abstract idea of labeling different molecules with different labels. *Id.* at claim 6. Each of these steps are expressly admitted to be known, routine laboratory techniques (both individually and as an ordered combination). In fact, the specification admits that tags (i.e., labels) have previously been used in combination even with "next-generation sequencing methods"—a procedure that requires attaching the tags, amplifying the DNA, and then sequencing (and thus detecting) the DNA. *Id.* at 2:31-34 ("Tagging approaches have also been used in combination with next-generation sequencing methods."); *see also id.* at 23:43-46; 33:7-11.

The "attaching" step is repeatedly described as being accomplished through "ligation", a technique the Fodor patents admit was known. *Id.* at 24:4-6 ("The label-tag may be attached to the target by any method available. In one embodiment, the label-tag is attached by ligation of the label-tag to one of the ends of the target.");<sup>8</sup> 9:7-30 (stating that "Methods of ligation will be known to those of skill in the art and are described, for example in Sambrook et at. [sic] (2001) and the New England BioLabs catalog both of which are incorporated herein by reference."); *see also*, *id*. at 6:25-47, 24:20-29, and 24:52-54 (further describing known ligation methods).

"Amplifying" DNA and other nucleic acid molecules is similarly described as known and the specification lists numerous example conventional amplification techniques. *See, e.g., id.* at 8:6-25 (stating that "[p]rior to or concurrent with analysis, the genomic sample may be amplified

<sup>&</sup>lt;sup>8</sup> The 857 patent deletes the first of these two sentences. *See* 857 patent at 30:51-52.

by a variety of mechanisms, some of which may employ PCR" and then citing and incorporating by reference multiple articles from the 1990s regarding PCR amplification); 7:13-34 (similar); 8:26-46 (identifying and citing prior art references describing multiple other known "suitable amplification methods"); and 8:56-9:6 (also describing other known amplification methods).

Multiple routine, conventional "detecting" techniques are similarly admitted. *Id.* at 32:27-28 ("Any available mechanism for detection of the labels may be used."); 6:25-47 ("The practice of the present invention may employ, unless otherwise indicated, conventional techniques ... *Such conventional techniques include* polymer array synthesis, hybridization, ligation, and *detection of hybridization using a label.*"); 2:15-34 (admitting that even detection of labeled or tagged nucleic acid molecules was known, explaining that "[b]oth digital and non-digital hybridization-based assays have been implemented using oligonucleotide tags that are hybridized to their complements, typically as part of a detection or signal generation schemes . . ." and identifying prior art articles about that dating back to 1988); 20:46-49 ("Digital PCR is an absolute counting method where solutions are stochastically partitioned . . . then detected by PCR."); 3:16-21 and 12:40-13:5 (further describing digital PCR and citing prior art articles about it); *see also* 1:37-44; 2:45-47; 2:53-56; 32:53-33:3 (further disclosing known "detecting" techniques).

The other claims of the Fodor patents fare no better than claim 6 of the 358 Patent and similarly add (at most) only generic, routine, conventional elements that are insufficient to render the claims "significantly more" more than the abstract labeling idea itself. Again, this also confirms the representativeness of claim 6 for this Motion. For example, beyond the steps already addressed for claim 6 of the 358 patent, claim 1 of the 857 patent claims that the "label-tag" "comprises nucleotides selected from purine bases, pyrimidine bases, natural nucleotide bases" or a variety of other base types, but the specification again admits that such tags were known and conventional. 358 patent at 2:15-26 ("Both digital and non-digital hybridization-based assays have been

implemented using oligonucleotide tags" and citing articles back to 1988); 14:5-47 (describing "oligonucleotide" and "nucleic acid" as being made of the base types listed in 857 patent claim 1).

Claim 1 of the 808 and 502 patents additionally claim "sequencing" steps. The Fodor patents similarly admit that sequencing was known and conventional. 358 patent at 2:31-34 ("Tagging approaches have also been used in combination with next-generation sequencing methods."); 2:45-47 ("many analytical methods have been developed to measure the relative abundance of different molecules through sampling (e.g., microarrays and sequencing)"); 20:31-33 ("Microarray and sequencing technologies are commonly used to obtain relative abundance of multiple targets in a sample."); 13:1-5 (use of Digital PCR to quantify sequencing libraries).

Claim 1 of the 137 patent additionally claims attaching and extending "primers" to produce double-stranded labeled nucleic acids; however, the specification admits such "hybridization" techniques, as well as PCR that involves binding and extending primers, were known and were used with label tags. 358 patent at 13:23-51 (describing "hybridization" as known and as "the process in which two single-stranded polynucleotides bind . . . to form a stable double-stranded polynucleotide"); 2:15-29 and 2:53-56 (describing "hybridization-based assays" and "PCR, hybridization" as known and implemented "tags that are hybridized to their complements").

Claim 1 of the 809 patent claims, apart from the abstract labeling idea, "an oligo dT sequence" and "a sequencing primer binding site" but again the Fodor patents admit the use of oligo dT sequences and primer binding were known and conventional. 358 Patent at 24:47-54 (describing known ligation techniques including use of oligo dT and citing a 1992 article); *id.* at 24:4-46 (describing known ligation techniques and identifying prior art dating back to 1983).

Claim 1 of the 808, 502, and 659 patents each claim that "the ratio of the number of diverse label-tag sequences to the number of occurrences of a target molecule is greater than 5." 808 patent at claim 1; see also, 502 and 659 patents at claim 1. However, the specification confirms that ratio

selection is just performing math (358 patent at 19:54-20:7), and is thus itself an ineligible abstract idea that cannot save these claims. *See In-Depth Test*, 2018 WL 6617142, at \*5 (finding step of "identifying" data "that fall[s] within control limits" to be "essentially 'doing math'" and thus an abstract idea); *see also Parker v. Flook*, 437 U.S. 584, 594-595 (1978) (formula for calculating alarm limits unpatentable); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (claims directed to a mathematical formula ineligible); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1168 (Fed. Cir. 2018) (finding abstract and ineligible claims directed to "the selection and mathematical analysis of information"); *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (similar). The dependent claims requiring attaching of the labels to be "stochastic" (*e.g.*, 358 patent claims 7 and 16; 857 patent claim 17; 808 patent claim 23; 137 patent claim 32; 502 patent claim 24) fail *Mayo* step 2 for the same reason—the specification admits that stochastic attachment is itself a mathematical abstract idea that was well known for more than 40 years. 358 patent at 21:32-40, 15:48-17:50.

Claim 6 of the 659 patent additionally claims "reaction vessels" and "processing software", but again these generic limitations are admitted to be conventional and routine by the specification.

358 patent at 9:51-10:8 (describing multiple known computer implemented methods and identifying prior art regarding counting and working with nucleic acid data); 10:52-11:22 (further describing prior art "conventional biology methods, software and systems" including "computer program products and software for a variety of purposes, such as probe design, management of data, analysis, and instrument operation"); 6:48-7:12 (describing conventional reaction vessels).

Ariosa and Mayo require finding these Fodor patents ineligible. Mere addition of conventional, routine techniques is insufficient to render the claims "significantly more" than the ineligible abstract idea under Mayo step 2. In Mayo, the added elements of administering the drug treatment and determining the metabolite levels were known, conventional steps that were

insufficient to save the claims. *Mayo*, 132 S. Ct. at 1296-97. Likewise, in *Ariosa*, the added elements of amplifying and determining the presence of a particular amino acid were "known laboratory techniques" insufficient to save the claims. *Ariosa*, 788 F.3d 1373-74; *see also Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 2019 WL 453489 (Fed. Cir. 2019). Judge Illston recently applied *Ariosa* and found invalid patents that, like the Fodor patents, add only routine, conventional steps to ineligible subject matter. *Illumina, Inv. v. Ariosa Diagnostics, Inc.*, No. 18-cv-02847-SI, 2018 WL 6735143, at \*6-8 (N.D. Cal. Dec. 24, 2018).

As in the cases of this Court addressed in the discussion of step 1 above (and as in *Ariosa* and *Mayo*), the Fodor patent claims fail to add "significantly more" to the abstract idea. Instead, they merely add conventional laboratory techniques in an attempt to limit the use of the abstract idea to the particular technological environment of DNA. The Fodor patents are thus invalid under § 101, *Alice*, and *Mayo*. BD's allegations in the Amended Complaint fail to overcome (and in fact contradict) the specification's admissions that the Fodor claim elements (apart from the abstract idea) were routine and conventional. "In a situation where the specification admits the additional claim elements are well-understood, routine, and conventional, it will be difficult, if not impossible, for a patentee to show a genuine dispute" sufficient to deny a motion to dismiss. *Berkheimer*, 890 F.3d at 1371; *see also TriPlay, Inc. v. WhatsApp Inc.*, No. 13-1703-LPS-CJB, 2018 WL1479027, at \*10 (D. Del. Mar. 27, 2018) ("[n]either the claims nor the specification explain what is inventive about [] the identifier, alone or in combination with other steps of the claims.").

# 3. BD's Assertions In The Amended Complaint Are Conclusory, Contrary To The Specification, And Insufficient To Salvage The Fodor Claims.

Faced with 10X's first motion to dismiss (D.I. 8), BD amended its complaint to add seven (largely duplicative) paragraphs to each count alleging infringement of the Fodor patents (D.I. 15, ¶¶ 94-100) in an attempt to manufacture a factual dispute to preclude resolution of § 101 eligibility at the motion to dismiss stage. However, multiple cases from this and other courts confirm that

these added pleadings are legally insufficient to salvage the Fodor patents even under a motion to dismiss posture. These amended pleadings fall into three categories—all insufficient to defeat 10X's motion: (1) boilerplate, conclusory assertions of the legal conclusion (D.I. 15, ¶¶ 96-100); (2) assertions that merely repeat language from the claims or specification (id., ¶¶ 94-95, 97); and (3) assertions of non-conventionality that are directly contrary to the specification (id., ¶¶ 97-98).

When considering a motion to dismiss, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Igbal, 556 U.S. 662, 678 (2009); Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) ("unsupported conclusions and unwarranted inferences" need not be accepted as true). BD's conclusory assertions—such as that various characterizations of the claims are "not an abstract idea" (¶ 96); "[s]killed artisans would understand that these benefits inure from the claimed inventions and inventive concepts" (¶ 97); "the steps recited in the claims of the '358 patent . . . were not well-understood, routine, or conventional" (¶ 98); "the additional limitations" of a laundry list of dependent claims "are not directed to an abstract idea and recite inventive concepts for additional reasons" (¶ 99); and that "claim 6 of the '358 patent is not substantially similar to nor linked to any abstract idea, much less the same abstract idea as [other asserted claims]" (¶ 100)—are precisely the type of boilerplate, conclusory attorney argument that this Court has found insufficient to defeat a motion to dismiss. IPA Techs., 2019 WL 259100, at \*10-12 (granting motion to dismiss, finding "boilerplate allegations" insufficient to establish eligibility, including assertions that "[t]he claimed inventions are directed to new computer functionality and improvements to technological processes . . . "); British Telecomms. PLC v. IAC/InterActiveCorp, No. 18-366-WCB, 2019 WL 438335, at \*20 (D. Del. Feb. 4, 2019) ("Aatrix and Berkheimer do

<sup>&</sup>lt;sup>9</sup> Citations here and below are to count 1 (¶¶ 94-100), but the arguments apply equally to the analogous corresponding paragraphs in the other Fodor counts of the Amended Complaint (D.I. 15,  $\P$ ¶ 119-125, 147-153, 178-184, 197-203, 224-230, and 248-254, respectively).

not stand for the proposition that a plaintiff can avoid dismissal simply by reciting in the complaint that the invention at issue is novel and nonconventional."); see also Uniloc USA, Inc. v. HTC Am., Inc., No. C17-1558JLR, 2018 WL 3008870, at \*9 (W.D. Wash. June 14, 2018) ("Simply stating that the claimed method and systems were not conventional at the time of the patent application does not make it so . . ."). BD's allegations "merely recite[] a boilerplate legal conclusion without any supporting facts in the remaining sections of the complaint, in the specification, or in the claims." See DiStefano Patent Tr. III, LLC v. LinkedIn Corp., 346 F. Supp. 3d 616, 625-26 (D. Del. Sep. 28, 2018) (dismissing under § 101, refusing to credit unsupported boilerplate assertions).

BD's other amended pleadings that simply incorporate language from the claims or specification (e.g., ¶¶ 94, 95, 97) are also insufficient to defeat 10X's Motion because "[t]hese allegations add no new factual information for the Court to consider in determining whether the claims contain an inventive concept." *IPA Techs.*, 2019 WL 259100, at \*10-12. Like the insufficient paragraphs added to the complaint in *IPA Technologies*, BD simply cites to and paraphrases the specification's statements about the prior art (D.I. 15, ¶ 94) and purported benefits (¶ 97), and quotes or repeats the language of the claims (¶ 95). *Compare* D.I. 15, ¶¶ 94-98 *with*, *e.g.*, **Ex.** E (*IPA Techs*. Complaint), ¶¶ 97-106, 111-12, 130, 132-34, 136, 153. Repeating language from the claims and specification adds no new factual information—and, here, the specification and claim language in fact confirm that the Fodor claims are ineligible under § 101.

Many of BD assertions in the Amended Complaint also contradict the specifications' own admissions regarding what was conventional in the art. *E.g.*, D.I. 15, ¶¶ 97-98. Complaint allegations are "not taken as true where they contradict admissions in the specification or the claims themselves." *IPA Techs.*, 2019 WL 259100, at \*5, 7, 10-12; *see also Berkheimer*, 881 F.3d at 1369-70 (improvements must be "captured in the claims"). For example, BD asserts that "quantitation of the abundance of molecules, e.g., nucleic acids, in a sample" was not conventional

(D.I. 15 ¶ 98), but the specification admits the opposite. 358 patent at 1:37-44 (discussing known techniques for "counting of tags or signatures of DNA fragments"); 20:46-49 (digital PCR was a known "absolute counting method"); 3:16-21 and 12:40-13:5 (further describing digital PCR). BD also asserts that "attaching diverse labels to target molecules" was not conventional (D.I. 15 ¶ 98), but the specification again admits the opposite. *Id.* at 9:7-30 (listing many known ligation methods for attaching labels). As in *IPA Technologies*, the Fodor "specification is replete with references to implementing the claims using conventional technology" and BD's unsupported contrary assertions cannot save the claims under § 101. *IPA Techs.*, 2019 WL 259100, at \*10.

# B. BD Fails To Plead Support For Some Counts As To Some 10X Products.

BD's Complaint defines "Accused Products" as 10X's Single Cell 3' Products, 5' Products, and Spatial Transcriptomics Products. D.I. 15, ¶¶ 91 and 19. Counts 4 and 8-12 of BD's Complaint assert that the "Accused Products" (broadly) infringe the Fodor 809 patent and all 4 of the Fan patents. *Id.*, ¶¶ 186-87, 189, 278-79, 294-95, 310-11, 328-29, 342-43. However, BD pleads *zero* facts supporting infringement of the 809 patent by 10X's Single Cell 5' Products or supporting infringement of any of the four Fan patents by the Spatial Transcriptomics Products. *Id.*, ¶¶ 188-89, 279-86, 295-302, 311-20, 329-34, 343-55. Counts 4 and 8-12 thus must be dismissed as to these products that are not supported by any pleadings. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Sipco, LLP v. Streetline, Inc.*, 230 F. Supp. 3d 351 (D. Del. 2017) (granting motion to dismiss where plaintiff merely identified its asserted patents and defendants' products); *North Star Innovations, Inc. v. Micron Tech. Inc.*, No. 17-506-LPS-CJB, 2017 WL 5501489 (D. Del. Nov. 16, 2017) (similar).

### VI. CONCLUSION

For the foregoing reasons, 10X respectfully requests that the Court dismiss counts 1-7 of the Complaint in full and dismiss counts 8-12 as to the Spatial Transcriptomics Products.

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